AMERICAN ACADEMY OF FAMILY PHYSICIANS

September 28, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Re: RIN 0945-AA17; Nondiscrimination in Health Programs and Activities

Dear Secretary Becerra:

On behalf of the American Academy of Family Physicians, representing 127,600 family physicians and medical students across the country, I write in response to the proposed rule "Nondiscrimination in Health Programs and Activities" as published in the August 4, 2022 version of the Federal Register.

The AAFP shares HHS' commitment to advancing health equity and ensuring all individuals, especially those belonging to historically underserved groups, receive accessible, respectful, and comprehensive healthcare. Family physicians provide comprehensive primary care that is focused on the whole person, individualized to the diverse needs of each patient, and provided longitudinally across a patient's lifespan. As such, family physicians are uniquely suited to identify shortcomings within our current healthcare system that result in inequitable access to care for individuals with disabilities, individuals with limited English proficiency (LEP), individuals with pregnancy-related conditions, and gender diverse individuals. The AAFP has detailed policy:

- Opposing patient discrimination in any form, including but not limited to, on the basis of actual or perceived race, color, religion, gender, sexual orientation, gender identity, ethnic affiliation, health, age, disability, economic status, body habitus or national origin,
- Supporting access to gender-affirming care for gender diverse patients, including children and adolescents,
- Supporting coverage of services for individuals requiring transition or transgender care,
- Opposing employer and health plan discrimination based on a patient's gender identity, sex assigned at birth, sexual orientation, marital status, or any other personal characteristic,
- Supporting reproductive decision-making between a patient and a physician, including referral to another physician if a patient's needs conflict with the physician's personal beliefs, and
- Supporting a physicians' right to not provide treatment or services that violates their personal beliefs, so long as adequate notice or a timely referral is offered.

With these principles in mind, the AAFP appreciates the opportunity to provide the following comments.

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Prohibited Discrimination (§ 92.101) and Application (§ 92.2)

Under this rule, protections against discrimination extend to a person's actual or perceived race, color, national origin, sex, age, and/or disability. HHS is proposing to clarify that discrimination on the basis of sex includes the basis of sex stereotypes, characteristics including intersex traits, pregnancy or related conditions, sexual orientation, and gender identity.

The AAFP agrees with this definition of prohibited discrimination and the clarification that sex-based protections include sexual orientation, gender identity, sex stereotypes, and pregnancy-related conditions. The AAFP also requests that HHS specify that "pregnancy-related conditions" includes termination of a pregnancy.

The AAFP strongly opposed the 2020 rule that weakened protections for lesbian, gay, bisexual, transgender, queer/questioning, and intersex (LGBTQI+) individuals and urged President Biden to reinstate the 2016 protections upon taking office. Access to gender-affirming care is critically important for the approximately 1.3 million individuals who identify as gender diverse (transgender, nonbinary, intersex, etc.). Those who receive gender-affirming care are less likely to attempt suicide, have lower rates of depression and anxiety, and use fewer illicit drugs.[i, ii] Yet gender diverse individuals continue to face disparities in access to health care services—nearly one in four transgender patients report avoiding needed medical care due to fear of stigma and discrimination, leading to higher health care costs and poorer outcomes.[iii] The AAFP's policy on care for the transgender and gender nonbinary patient supports access to gender-affirming care and the ability for physicians to refer patients if they are unable to provide this care. The AAFP supports HHS' efforts to further clarify that physicians are still able to decline to participate in a procedure under religious or conscience objections, and we appreciate that HHS has provided clear guidance on how an individual or organization can do so under § 92.302 of this proposed rule.

Additionally, HHS is proposing to apply this rule to all health programs and activities under HHS, except for an employer with regard to its employment practices, including the provision of employee health benefits. Other federal agencies would handle enforcement of non-discrimination provisions for these entities. HHS indicates in the preamble that, based on enforcement experience with the previous non-discrimination rules, this would reduce confusion and burden on individuals filing discrimination complaints.

The AAFP supports extending this rule to all activities under HHS, as this will ensure groups of individuals who currently and historically face higher rates of discrimination are appropriately protected and able to access care. The AAFP agrees with HHS' statement that it is also important to ensure that the over 55 percent of the U.S. population currently covered by employer-sponsored health plans also have appropriate protection from discriminatory action or benefit design.[iv] While this rule will not extend to those plans, most employer-sponsored health plans are required to comply with ERISA and HIPAA non-discrimination regulations from the Department of Labor (DOL) and Department of Treasury. The AAFP urges HHS to work with DOL, Treasury, and other appropriate agencies to ensure non-discrimination protections are applied and upheld under other federal regulation.

Notification of Views Regarding Application of Federal Conscience and Religious Freedom Laws (§ 92.302)

As mentioned above, HHS is proposing to establish a process in which an individual or organization may indicate that a provision of this regulation violates their federal conscience or religious freedom laws. Under this proposal, individuals or organizations will not be required to perform any activity that may conflict with their conscience and/or religious protections before the Office for Civil Rights (OCR) has made a determination about their claim.

The AAFP recognizes and respects the rights of health care professionals to decline to participate in non-emergency care that violates their personal code of ethics, so long as a physician makes an appropriate referral for the patient to seek that care elsewhere. **We appreciate HHS reaffirming conscience protections. The AAFP is also committed to ensuring all patients have access to health care, regardless of actual or perceived race, color, religion, gender, sexual orientation, gender identity, ethnic affiliation, health, age, disability, economic status, body habitus or national origin.** The AAFP makes a clear distinction between declining to participate in a procedure based on moral grounds versus denying access to care to an individual patient. Declining to participate in a procedure based on moral grounds is a protected right; declining to care for specific groups of people or individuals without adequate notice or an appropriate referral is an unacceptable shirking of health care professionals' responsibility to care for patients and is contrary to the key underpinnings of the Code of Medical Ethics.

The AAFP joined other medical societies in filing an amicus brief that distinguishes between legal requirements under emergency and non-emergency care. The Emergency Medical Treatment and Labor Act (EMTALA) requires that physicians provide treatment to any patient who presents with an emergency condition "until the emergency medical condition is resolved or stabilized."[v] EMTALA properly defers to the medical judgment of the physician(s) responsible for treating the patient to determine how best to achieve the designated objective of stabilization under established clinical guidelines and the latest advancements in medical science. Just as EMTALA does not specify particular treatments, it also does not allow for physicians to withhold specific treatments from particular patients for non-medical reasons. Rather, if a treatment is "required to stabilize the medical condition," it must be provided.[vi] When faced with a pregnant patient suffering from an emergency medical condition, in order to comply with EMTALA, clinicians must promptly provide stabilizing treatment to that pregnant patient. It is essential for physicians providing emergency care to have access to the full suite of interventions and treatments, consistent with evidence-based clinical guidelines—and they must be able to act without hesitation. Because pregnancy termination is part of the medically indicated treatment to stabilize patients in certain emergency scenarios, physicians—to comply with EMTALA and the principles of medical ethics—must, and do, consider abortion a necessary treatment option. **The AAFP encourages HHS to align exemptions under this provision with EMTALA's requirements under emergency medical conditions.**

Aside from aligning this section with EMTALA, the AAFP believes HHS' outlined process for conscience or religious objections allows physicians and organizations to make appropriate claims to protect their right to not provide specific procedures, while ensuring historically underserved individuals are still able to access the necessary, high-quality, respectful, and comprehensive care they need and deserve. However, the AAFP is concerned that delays in

the review process or a higher volume of claims may result in disruptions in care or inappropriate denials of care while an entity is awaiting a case decision. **To address this, the AAFP recommends HHS publish the anticipated timeframe for review of exemption claims, notify individuals and/or organizations when they anticipate their review to be complete, and instruct the individual/organization to notify patients if they will not be offering the service or treatment under review during that period.** The AAFP also recommends HHS publicize de-identified data on conscience claims and review timelines to ensure public and private entities can monitor any access issues, should they occur.

Meaningful Access for Limited English Proficient Individuals (§ 92.201)

HHS is proposing to require that covered entities take reasonable steps to ensure each individual with limited English proficiency (LEP) who is "eligible to be served or likely to be directly affected" has meaningful access to the entities' health programs and services. HHS has revised this language from the 2016 version of this rule to reference an LEP individual "directly affected" rather than "likely to be encountered" to provide additional clarity about the applicability of this rule and align the language with additional guidance and regulation. As consistent with previous iterations of this rule, HHS requires that these services be free of charge, accurate, and timely.

The AAFP supports HHS' efforts to ensure all individuals have meaningful access to health programs and services, regardless of language barriers, and this proposal is aligned with AAFP's position paper on providing culturally sensitive care. The AAFP also appreciates HHS' clarifying language around LEP individuals directly affected by a program or service, as opposed to "likely to be encountered." While this change from the 2016 rule is necessary and will reduce some burden on small or solo practices who may have otherwise struggled to meet the previous definition, it should be noted that providing translation services can be financially burdensome for primary care practices that already operate on thin margins. **With this in mind, the AAFP encourages HHS to use its authority to ensure funding is made available for interpreter services in primary care practices**. Current data indicates LEP individuals are less likely to be insured and less likely to have a usual source of care than those with full English proficiency.[vii] Ensuring equitable access to care requires support for LEP individuals and their physicians across programs and agencies.

To evaluate compliance with this section, HHS is proposing a case-by-case approach that takes into account the nature and importance or the health program or activity, and the implemented written language access procedures by a covered entity. Notably, this approach does not require entities to implement a formal language access plan, though HHS strongly encourages this approach, nor does it implement the 2020 rule's four-factor analysis.

The AAFP appreciates that HHS is proposing a case-by-case approach to evaluating compliance and is not requiring development or implementation of a formal language access plan. The AAFP strongly supports efforts by our members to provide appropriate language and communication assistance for their patients and recognizes that a formal language access plan may be necessary in some, but not, all cases. Oftentimes, a formal plan requires significant time, administrative effort, and financial resources that are not available for small and solo practices; the 2015 proposed rule estimated $1,135 per small entity to comply

the formal previous formal requirement. **As such, the AAFP supports HHS finalizing this compliance provision as proposed.**

HHS is also proposing to require covered entities to use a qualified human translator to review materials that have been translated using machine translation. This would apply when the underlying text "is critical to the rights, benefits, or meaningful access of an LEP individual; when accuracy is essential; or when the source documents or materials contain complex, non-literal, or technical language." OCR seeks comment on this proposal and whether there should be exceptions or other approaches to address inaccurate machine translations.

The AAFP has concerns about the availability of human translators and unfeasibility of this provision for most independent practices. If implemented as proposed, this provision will likely place additional burden on smaller practices that provide care to underserved populations. The AAFP suggests HHS instead encourage entities to make reasonable efforts to ensure that machine translations are accurate and appropriate. If HHS instead chooses to finalize this proposal, the AAFP recommends HHS provide free human translation services for physician practices that are unable to find or pay for human translation services.

HHS also proposes to adopt standards for video remote interpreting (VRI) and audio remote interpreting (ARI). The AAFP supports adoption of attainable standards to ensure implementation of VRI and ARI is appropriate and accurate for patients and individuals reliant on these services.

Effective Communication for Individuals with Disabilities (§ 92.202)

HHS is proposing to expand existing requirements for communication for individuals with disabilities to also include an individual's companion with disabilities. This is consistent with regulations under Title II of the Americans with Disabilities Act (ADA). HHS is also proposing to extend existing requirements for auxiliary aids and services for individuals with impaired sensory, manual, or speaking skills to apply to all covered entities as opposed to just recipients or State Exchanges.

The AAFP supports extending the communication requirement to include companions with disabilities and appreciates HHS streamlining regulations with existing requirements under the ADA. The AAFP supports shared decision-making in healthcare, which primarily includes decision-making between a physician and a patient but can extend to the patient's family or other support if desired by the patient.[viii] Extending communication requirements to include companions will facilitate shared decision making that is inclusive of patients' companions, family members, or caregivers when appropriate.

Accessibility of Information and Communication Technology (ICT) for Individuals with Disabilities (§ 92.204)

HHS is proposing to require that programs and activities provided through information and communication technology (ICT) are accessible to individuals with disabilities or provide alternative access to the information if compliance would result in undue financial and

administrative burdens or a fundamental alteration in the nature of the health programs or activities.

The AAFP supports the requirement that programs and activities provided through ICT are accessible to individuals with disabilities. We urge OCR to work with small, independent, or otherwise under-resourced physician practices to ensure they have the resources, financial assistance, and tools needed to effectively provide accessible programs and activities to patients with disabilities.

OCR is seeking comments on whether the Section 1557 rule should include a provision requiring covered entities to comply with specific accessibility standards, such as the Web Content Accessibility Guidelines (WCAG) developed by the Web Accessibility Initiative. OCR is also seeking comment on whether to adopt a safe harbor provision under which covered entities that are in compliance with established specific accessibility standards are deemed in compliance with this section; whether OCR should require covered entities to comply with the most recent edition of a published standard; and the timeline necessary for covered entities to come into compliance with a new standard.

The AAFP supports compliance with accessibility standards, so long as OCR conducts real-world testing with successful results in a variety of physician office environments before any implementation and required compliance with accessibility standards. Real-world testing must be conducted across a variety of physician practice types, sizes, geographical areas, and patient populations, including patients with different abilities. Leveraging the input of physicians and their support staff throughout the standards development and implementation process can better support the needs of both physicians and their patients and determine how compliance can best be met. **This real-world testing should inform when and which level of compliance should be required and the timeline for moving forward.**

Moreover, HHS must work with the Office of the National Coordinator for Health Information Technology (ONC) and vendors to ensure compliance with these standards does not place undue financial or administrative burden on practices. Primary care practices are already facing financial uncertainty and regulatory burdens that reduce the amount of time physicians can spend caring for their patients.[ix] The AAFP agrees these standards are important and necessary, but mandating compliance with new tech standards without also ensuring meaningful, affordable access for physician practices will make it unattainable for many practices and prevent widespread adoption.

Additionally, physician practices may already be working with vendors to accomplish ICT accessibility for individuals with disabilities. The AAFP urges OCR to implement exceptions for situations in which practices are working to accomplish accessibility with existing technologies or in cases where the vendor physician practices are working with does not provide a version that is compliant with any adopted standards, including the WCAG. If compliance with a specific set or edition of standards is required (e.g., the WCAG), the AAFP recommends OCR consider applying the exception for financial hardship to physician practices who are already working with a vendor on different accessibility standards or working with a vendor that is requiring significant upgrade costs to come into compliance.

Moreover, physicians are not solely responsible for the accessibility of their ICT. Physicians work with a variety of technology companies to provide their patients with a virtual platform –

such as telehealth services, websites, and mobile applications – that enhance their patient care experience. **OCR should consider ways to incorporate technology companies alongside physicians in standards compliance and responsibility for ensuring accessible ICT for people with disabilities.**

Equal Program Access on the Basis of Sex (§ 92.206)

HHS is proposing to clarify that covered entities may not deny or limit health services on the basis of sex, "including those that are offered exclusively to individuals of one sex, to an individual based on the individual's sex assigned at birth, gender identity, or gender otherwise recorded." HHS provides a clarification about what actions would be discriminatory and therefore would be prohibited, including but not limited to:

- Denial or limitation of a health service based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded, including those that are exclusively offered to individuals of one sex,
- An entity restricting a health professional's ability to provide care based on their patient's sex assigned at birth, gender identity, or gender otherwise recorded, including punishing or discipling a provider for providing clinically appropriate care,
- Separating or treating individuals based on their sex in a manner that subjects them to more than *de minimis* harm, a legal definition meaning having no more than minimal impact:
    - HHS gives the example that providing a clinical treatment to a patient based on their currently present sex characteristics is generally not more than *de minimis* harm,
- Denying or limiting gender-affirming care that would otherwise be provided for another purpose.

HHS further proposes to clarify that health professionals are not required to provide any service when it is deemed not clinically appropriate for that individual patient, or for other non-discriminatory reasons. HHS further notes that compliance with state or local laws does not constitute sufficient judgement for a basis that a service is not clinically appropriate.

The AAFP supports the majority of this proposal and finds the clarification to be necessary to eliminate sex-based discrimination. The AAFP agrees that physicians should not be compelled to provide services when they determine on an individual basis that it is not clinically appropriate. **However, our interpretation of the proposed rule is that a physician's conduct may be considered discriminatory if they refuse to provide a service that may be clinically appropriate but is banned by (or otherwise in violation of) state or local law.** This provision would place physicians in an impossible position by either requiring that they violate state or local laws or face possible penalties for violating federal non-discrimination regulations.

The AAFP opposes the categorical bans on gender-affirming care and abortion in states because of the interference with evidence-based medicine and the patient-physician relationship. Moreover, it is clear that the criminalization and penalization of patients and clinicians disrupts and detracts from medical care. Unfortunately, requiring physicians to violate

state and local laws in order to comply with this regulation will not meaningfully protect patients from the negative impacts of these harmful laws. Under some state laws, physicians who provide services addressed in this provision face time and cost-consuming lawsuits, criminal charges, loss of their medical license, and other negative ramifications which take physicians away from their practice and their patients. The AAFP appreciates HHS' efforts to minimize the harm of state and local regulations and bans on evidence-based care, but finalizing this provision will not achieve this goal. Further, HHS has not provided clear guidance or legal support to protect physicians providing evidence-based health care. **Therefore, the AAFP strongly urges HHS to clarify in the final rule that physicians who decline to provide clinically appropriate non-emergency services, in order to comply with state and local laws will not be considered discriminatory nor penalized under federal non-discrimination regulations. We also request HHS provide clarification, guidance, and support for physicians navigating compliance with changing federal, state, and local regulations when compliance with this and other federal regulations and guidance contradicts state or local laws.**

OCR seeks comment on what sex-based distinctions, if any, should be permitted in the context of health programs and activities, and whether additional regulatory language should be added to specifically address the circumstance in which a provider offers a particular health treatment, service or procedure for certain purposes, but refuses to offer that same treatment, service or procedure for gender-transition or other gender-affirming care purposes because they believe it would not be clinically appropriate.

The AAFP believes an individualized-approach to gender-affirming care is appropriate in all contexts. The AAFP also believes that the provision of any care, especially preventive care, should be based on the patient's current anatomy, with verbal affirmation of a patient's gender identity. As proposed, this provision allows for medically appropriate care and shared decision making between a patient and a physician. The AAFP also appreciates that HHS provides a detailed explanation of *de minimis* harm and the difference between clinical care for a patient based on their anatomy and verbal or other forms of affirmation of their gender identity.

OCR seeks comment on if this section adequately addresses the forms of pregnancy-related discrimination. **The AAFP recommends HHS provide additional clarifications or examples of prohibited discriminatory behavior or action directed toward an individual who has experienced or received treatment for a pregnancy-related conditions.** However, we again note that any finalized language should not place physicians in the impossible position of either violating federal regulations or state and local laws.

Nondiscrimination in Health Insurance Coverage and Other Health-Related Coverage (§ 92.207)

HHS proposes to reinstate prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability by health insurance plans or related coverage by addressing benefit design. Under this proposal, a covered entity would not be able to provide a categorical exclusion or limitation for all gender transition or gender-affirming care when not applied to the same services provided for other reasons. Under (b)(3) of this section, HHS clarifies that a health insurer may inquire about an individual's relevant medical history and physical traits to determine medical necessity of a service.

The AAFP finds the majority of this proposal to be appropriate and necessary to ensure access to gender-affirming care, but we have concerns with the proposal to allow health plans to use prior authorization, step therapy, and durational or quantity limits to care when applied in nondiscriminatory manners. The decision about the medical necessity of a service or procedure should be made between a patient and their physician. Under this provision HHS clarifies that issuers can use prior authorization, step therapy, and durational or quantity limits to care when applied in nondiscriminatory manners. The AAFP recognizes that health plans use these strategies to contain costs by restricting access to expensive services or treatments. However, these strategies result in administrative burden for physicians and the aforementioned delays in care for patients. There is some evidence to suggest that prior authorization worsens health disparities, and the AAFP is concerned that prior authorization may be used inappropriately as it relates to gender-affirming care.[x, xi]

Family physicians using appropriate clinical knowledge, training, and experience should be able to prescribe medications and order medical equipment without being subjected to prior authorizations. In the rare circumstances when a prior authorization is clinically relevant, the AAFP believes the prior authorization must be evidence-based, transparent, and administratively efficient to ensure timely access to promote ideal patient outcomes. The AAFP further believes step therapy protocols, in which insurers encourage less expensive prescription drugs to be prescribed prior to more costly alternatives, delay access to treatment and hinder adherence.[xii] Therefore, step therapy should not be mandatory for patients already on a working course of treatment and generic medications should not require prior authorization. Ongoing care should continue while prior authorization approvals or step therapy overrides are obtained, and patients should not be required to repeat or retry step therapy protocols that failed under previous benefit plans. The AAFP strongly urges HHS to use its existing authority to help streamline prior authorization, step therapy, and durational or quantity limits to care and hold health plans accountable for timely responses and actions on the aforementioned measures. To minimize care delays, **HHS should also work with ONC and EHR vendors to ensure physicians can clearly differentiate between anatomy and gender-identity in a patient's EHR and in communication with a patient's insurance provider in a way that does not harm the patient.**

HHS is also proposing to require health insurance coverage to provide the most integrated setting appropriate to the needs of individuals with disabilities. The AAFP strongly supports this proposal because health insurance and payment should not interfere with a patient's equitable access to medically necessary, evidence-based clinical care.

OCR is also seeking comment on how section 1557 might apply to provider networks and network adequacy, particularly as it relates to individuals with disabilities.

The AAFP provided detailed comments for the 2023 Notice of Benefit and Payment Parameters, which included the AAFP's suggestions for improving network adequacy standards, such as by implementing time and distance standards and incorporating wait time data. The AAFP agrees that network adequacy should take into account accessible medical equipment for individuals with disabilities, as well as language and translation accessibility for LEP individuals and individuals with disabilities. HHS should require that plans take reasonable steps to make accessible care available within established time, distance, and wait time standards.

Prohibition on Sex Discrimination Related to Marital, Parental, or Family Status (§ 92.208)

HHS is proposing to align 1557 protections with Title IX protections, which prohibit discrimination on the basis of sex with respect to an individual's marital, parental, or family status. OCR is considering including a provision on the basis of pregnancy-related conditions and how to do so.

The AAFP strongly supports HHS clarifying that discrimination related to marital, parental, or family status includes pregnancy-related conditions, including the decision to terminate a pregnancy.

Nondiscrimination on the Basis of Association (§ 92.209)

HHS is proposing to reinstate the 2016 provisions prohibiting discrimination against an individual on the basis of the race, color, national origin, sex, age, or disability of an individual with whom the individual is known to have a relationship or association. This provision ensures that individual cannot be discriminated against or denied healthcare services or programs solely because of the identity of their spouse or other members of their family or other association.

The AAFP supports reinstating this provision and strongly opposes all discrimination, including that on the basis of actual or perceived race, color, religion, gender, sexual orientation, gender identity, ethnic affiliation, health, age, disability, economic status, body habitus or national origin. Therefore, we encourage HHS to finalize this provision as proposed.

Use of Clinical Algorithms in Decision-Making (§ 92.210)

HHS is proposing to prohibit discrimination under clinical algorithms by holding covered entities liable for any decision made when relying on a clinical algorithm if the intent or result is discriminatory. Covered entities would not be liable for the algorithm itself, only any decision and the impact of such decision.

The AAFP supports OCR's proposal to prohibit discrimination using clinical algorithms and supports expanding this proposal beyond just clinical algorithms to include artificial intelligence and machine learning (AI/ML). While the AAFP believes that AI/ML have potential to improve outcomes for patients, we strongly support efforts to harness this technology and we recognize the limitations and pitfalls of this technology.

Recent studies indicate clinical guidance and existing algorithms for clinical decision making may be based on biased studies and exacerbate inequities.[xiii] One study found an algorithm used in hospitals systematically discriminated against Black patients.[xiv] Experts also predict that rapid implementation of AI-solutions amid the COVID-19 pandemic may widen the already disparate impact of the virus.[xv] To improve trust in and equitability of AI/ML solutions, discriminatory outcomes must be addressed before successfully integrated AI/ML into clinical care. It is essential that AI-based technology augment decisions made by the user, not replace their clinical judgment or shared decision-making.

The AAFP supports the approach of OCR working with covered entities on suggested actions to mitigate potential discriminatory outcomes. These actions may include testing of algorithms before and during use and corrective action plans with efficient and achievable steps to take when error is discovered. An approach of initial warning and corrective action would be far more effective than penalization. Such a learning environment allows physicians to work in good faith to improve the use of algorithms and may contribute to their full understanding of the creation and use of algorithms and their effects on patient care. Additionally, it is critical that algorithm developers and evaluators are transparent with physicians on the creation, evaluation, adjustment, and data collection on clinical algorithms. This gives physicians and other clinicians more opportunity to address implicit biases and determine if use of the algorithm is appropriate for a particular patient case. We appreciate ONC's consideration of clinicians' need for more transparency of AI/ML tools and the evaluation of such tools in various care settings. We urge ONC to make this information readily available and adaptable for clinicians' use without introducing additional burden on physicians to use it in practice.

With this in mind, **OCR should also consider the varying levels of liability that correspond with different medical scenarios.** Physicians should not be expected to evaluate the efficacy and safety of individual clinical algorithms while providing patient care, and therefore should not be held solely liable for the consequences of these algorithms. This is especially true if physician practices do not have the appropriate technology available to evaluate the algorithms in real-time. **The AAFP recommends liability for the consequences of the use of clinical algorithms be shared between the clinician and the algorithm creator.** This may be modeled on the risk framework proposed in the Food and Drug Administration Safety and Innovation Act (FDASIA), in which the FDA collaborated with FCC and ONC, along with solicited stakeholder input, to form best practices on an appropriate, risk-based regulatory framework that promotes innovation, protects patient safety, and avoids unnecessary and duplicative regulation.

In any case, individual review of each clinical decision is necessary. Decisions should be made according to clinical judgment and shared decision making, and supported by algorithms, not replaced by them. **The AAFP believes implicit bias among both physicians and health care researchers must be addressed and implicit bias training should be implemented to support culturally appropriate, patient-centered care and reduce health disparities.** This should include bias training related to the creation, use, and individual review of clinical algorithms to improve care delivery and the success of the algorithms.

OCR should provide covered entities, specifically physician practices, with technical assistance and guidance to help integrate both clinical algorithms and improvements for these algorithms into existing clinical workflows to increase efficiency and minimize administrative burden. This should include any required participation in governance, transparency, reporting, and impact assessments. OCR may consider working with ONC and the CMS Office of Burden Reduction and Health Informatics to accomplish this in a way that is efficient and sustainable for covered entities. OCR may consider providing template reporting structures or examples of how to continually evaluate algorithms and track their impacts on patients both during the process of use, immediate outcomes, and long-term outcomes for physician practices to use.

Nondiscrimination in the Delivery of Health Programs and Activities Through Telehealth Services (§ 92.211)

HHS is proposing to require that covered entities provide telehealth services in a manner that does not discriminate on a protected basis and provides effective communication for individuals with disabilities and limited English proficiency (LEP). OCR is seeking comment on this approach and whether covered entities and others would benefit from a specific provision addressing accessibility in telehealth services. OCR is also seeking comment on challenges with accessibility specific to telehealth and recommendations for telehealth accessibility standards that would supplement the ICT standards (proposed § 92.204) and effective communication requirements (proposed § 92.202).

The AAFP supports the proposal to require covered entities to provide telehealth services in a manner that does not discriminate on a protected basis and provides effective communication for individuals with disabilities and LEP. The Academy appreciates and supports the recent HHS Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons. The growth of telehealth as a modality of care delivery during the COVID-19 pandemic reinforces the need to ensure this technology is accessible to all patients, including people with disabilities and those with limited English proficiency. The AAFP has long advocated that the use of telehealth be expanded as an appropriate and efficient means to enhance patient-physician collaborations, increase access to care, improve health outcomes by enabling timely care interventions and decrease costs. Telehealth policies should be designed to support existing patient-physician relationships and refrain from enabling virtual only/DTC telehealth companies to expand and inhibit in-person care.

We encourage HHS and OCR to consider ways to support small, independent practices with the resources, tools, and technology to effectively ensure telehealth services are accessible for these populations without undue financial or administrative burden. We also encourage OCR to collaborate with Congress to create a pilot program to fund digital health literacy programs for patients, digital health navigators, point-of-care interpretive services, digital tools with non-English language options, and tools with assistive technology. The AAFP has advocated for further studies of telehealth policies to determine whether they are improving access to care for underserved communities, protecting patient safety, and advancing health equity, including for those with disabilities and LEP.

Similarly, the AAFP recognizes the disparities between individuals with access to broadband internet compared to those without it. Many patients experience technology and infrastructure barriers to using video telehealth visits, making audio-only a valuable method to accessing care. The lack of modern broadband infrastructure has proven to be a primary barrier to equitable telehealth and digital health access for rural Americans, who are 10 times more likely to lack broadband access than their urban counterparts, leading to fewer audio/video visits.[xvi, xvii, xviii] There also exist disparities in access to technology that is essential for successful video telehealth visits. One in three households headed by someone over the age of 65 do not have a computer and more than half of people over age 65 do not have a smartphone.[xix] A report from the Assistant Secretary for Planning and Evaluation (ASPE) also found that Black, Latino, Asian, and elderly patients, as well as those without a high-school diploma, were more likely to rely on audio-only telehealth visits.[xx] **The AAFP urges HHS to work with Congress to ensure**

the implementation of permanent telehealth policies ensures coverage of and fair payment for audio-only telehealth services. This is essential to facilitate equitable access to care after the PHE-related telehealth flexibilities expire.

Thank you for the opportunity to comment on the proposed rule. The AAFP would also like to raise our policies on data collection, patient discrimination, and coverage equity that may be helpful to HHS and OCR as this rule is finalized. If you have additional questions, please contact Morgan Bailie, Senior Regulatory Specialist, at mbailie@aafp.org.

Sincerely,

Sterling Ransone, Jr., MD, FAAFP
Board Chair, American Academy of Family Physicians

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[i] Grant, J.M., Mottet, L.A., Tanis J. Injustice at Every Turn : A Report of the National Transgender Discrimination Survey. *Washington: National Center for Transgender Equality and National Gay and Lesbian Task Force*. 2011;(May):120-198.

[ii] American Medical Association. Issue brief: Health insurance coverage for gender-affirming care of transgender patients. 2019;04(May 2017):1-5. https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf

[iii] Seelman, K. L., Colón-Diaz, M., LeCroix, R. H., Xavier-Brier, M., & Kattari, L. (2017). Transgender Noninclusive Healthcare and Delaying Care Because of Fear: Connections to General Health and Mental Health Among Transgender Adults. *Transgender health*, *2*(1), 17–28. https://doi.org/10.1089/trgh.2016.0024

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